

(21) Application No. 827790A

(22) Date of filing 09.04.1992

(71) Applicant

Bayer AG

(Incorporated in the United Kingdom)

Bayer Wey, North Lynn Industrial Estate,
King's Lynn, Norfolk, PE30 3AA, United Kingdom

(72) Inventors

Wolfgang Bartschewski
Adam Karbowiak
Paul Karsner

(73) Agent and/or Address for Service

Smith Wade Tassart
17 Finsbury Square, London, EC2A 1PQ,
United Kingdom

(31) INT. CL.

A61M 15/00

(52) UK CL. (Edition 1)

A61M 15/00 T102 T11X
P1A F02

(53) Documents cited

None

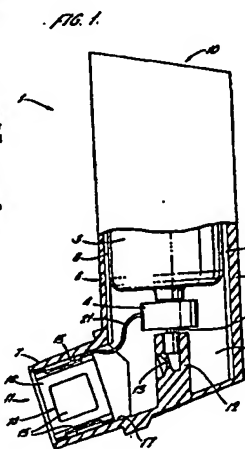
(54) Field of search

UK CL. (Edition 1) A61M 15/00 T102 T11X
P1A F02

(54) Inhalation apparatus

(57) An inhaler 1 has a housing 2 defining a passageway 9 for inhaled air. An aerosol dispenser 3 is arranged to be responsive to an electrical actuating signal to dispense into the passageway a substance to be inhaled. A sensor 14 produces the actuating signal in response to inhalation and comprises a membrane 15 of a piezoelectric material, such as PVDF, arranged to produce a signal voltage in response to flexure. A support member 18 holds the membrane in position relative to the housing at a location such that the membrane flexes in response to a change of air pressure in the passageway. The inhaler is primarily intended for medical dispensing of inhaled substances.

As shown in Fig. 1, the membrane 15 normally lies in contact with a slide wall 17 defining the passageway 9. In another embodiment, (Fig. 4), the membrane (54) is bonded to and flexes with an elastic diaphragm (53) exposed on one side to ambient air and on the other to air within the passageway.



GB 2 266 466 A

FIG. 1.

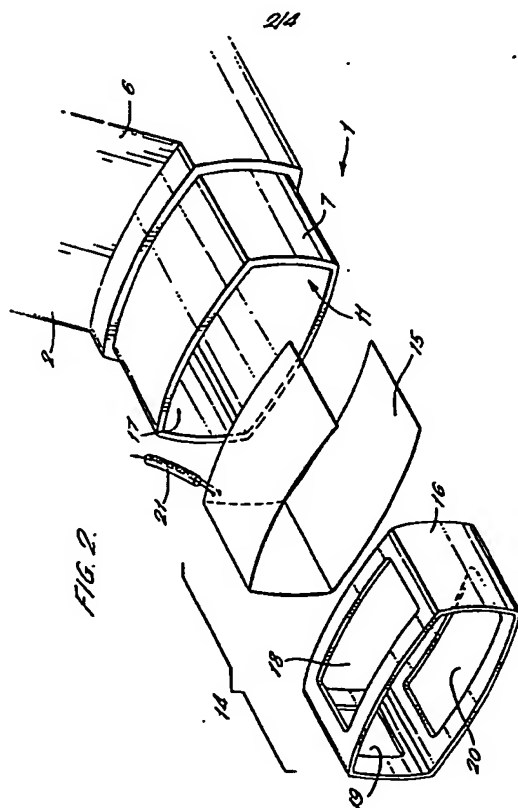
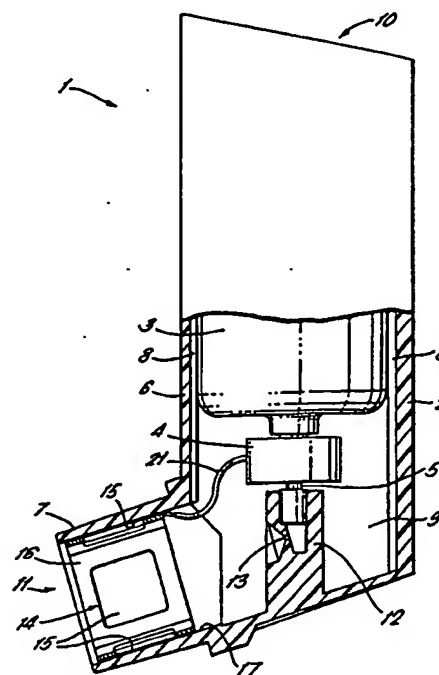
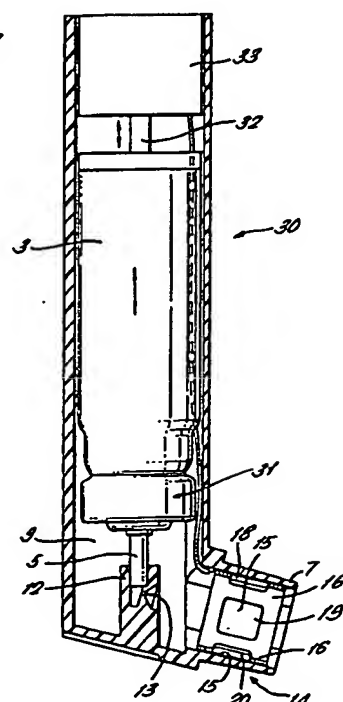


FIG. 3.



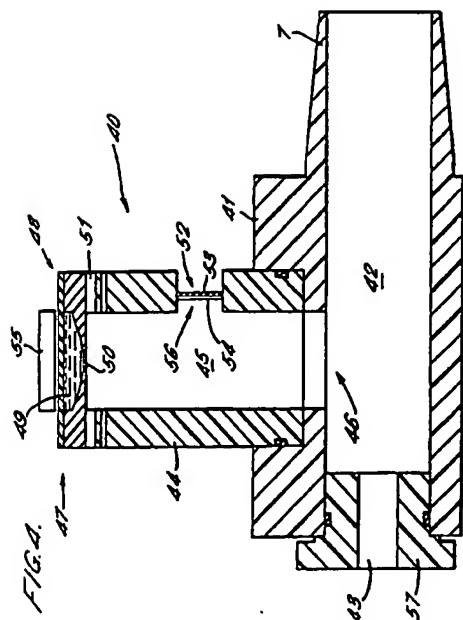
"INHALATION APPARATUS"

This invention relates to inhalation apparatus for dispensing inhaled substances and in particular but not exclusively to dispensing of medicinal products in aerosol form from a pressurised dispensing container.

It is known to provide a sensor in an inhalation apparatus to detect inhalation by a user in order to synchronise with inhalation the release into the inhaled air flow of a substance to be inhaled. It is for example important in the administration of aerosol products for the relief of asthma that the timing of the dispensing operation should be carefully controlled to ensure maximum disposition of the substance in the user's lungs.

It is known from WO87/04354 to provide an electrically operated dispensing means responsive to a signal generated by a sensor which is responsive to the flow of air through a passageway. A hinged flap cooperates with a reed contact to make electrical contact and generate an actuating signal for the dispensing means.

According to the present invention there is disclosed inhalation apparatus for dispensing inhaled substances comprising a housing defining a passageway for inhaled air, a dispensing means operable in response to an electrical actuating signal to dispense into the passageway a substance to be inhaled, and a sensor operable to produce the actuation signal in response to inhalation wherein the sensor comprises a membrane of piezoelectric material and support means supporting the membrane relative to the housing at a location such that the membrane flexes in response to a change of air pressure in the passageway to thereby generate the



- 2 -

actuation signal.

An advantage of such apparatus is that it provides a sensor of simple construction and which is relatively easy to assemble with the housing. A further advantage is that the sensor generates an actuation signal by piezoelectric action which does not require the sensor to be energised from an external electrical source.

Preferably the membrane comprises a flexible polymeric piezoelectric material such as polyvinylidene fluoride (PVDF).

Conveniently the support means comprises a support member cooperating with the housing to clamp a clamped portion of the membrane in fixed relationship with the housing, the clamped portion being peripheral to at least one unclamped portion which is flexible in response to pressure change in the passageway.

Preferably the membrane overlies a portion of a side wall defining the passageway.

The member may alternatively be mounted on a resilient diaphragm for flexure in unison with the diaphragm, the diaphragm being located such that one side of the diaphragm is exposed to ambient air pressure and the other side of the diaphragm is exposed to air within the passageway.

Preferred embodiments of the present invention will now be described by way of example only and with reference to the accompanying drawings of which:-

Figure 1 is a part sectioned elevation of an inhalation apparatus;

Figure 2 is an exploded perspective view of the apparatus of Figure 1;

Figure 3 is a part sectioned elevation of an alternative apparatus; and

Figure 4 is a sectioned elevation of a further

- 3 -

alternative apparatus.

Apparatus 1 of Figure 1 comprises a generally tubular housing 2 receiving a cylindrical pressurised dispensing container 3. The container 3 has an electrically operated outlet valve 4 which is operable to release a metered dose of a medicinal product through a valve stem 5 in response to an electrical actuating signal.

The housing 2 consists of a main tubular portion 6 which receives the container 3 and a mouthpiece 7 projecting laterally from the lower end of the main tubular portion. The main tubular portion 6 includes circumferentially spaced ribs 8 which project inwardly so as to space the container 3 from the housing 2 to allow air to flow around the container 3. An air passageway 9 is defined by the housing 2 and extends from an open end 10 of the housing, through the main tubular portion 6 and through the mouthpiece 7 to an outlet 11.

The valve stem 5 is received in a nozzle fitting 12 having a nozzle opening 13 arranged to direct an aerosol spray from discharge through the valve in a direction towards the outlet 11.

A sensor 14 is located in the mouthpiece 7 and comprises a piezoelectric membrane 15 which is held by a support member 16 so as to normally lie in contact with an annular side wall portion 17 of the mouthpiece 7.

As shown more clearly in Figure 2 the support member 16 is generally tubular in shape and fits snugly within the mouthpiece 7. The support member 16 is provided with cut-outs 18, 19 and 20 through which corresponding unclamped portions of the membrane 15 are exposed, each exposed portion of the membrane being surrounded by an annular clamped portion which is overlaid by the support member 16

and clamped in contact with the side wall portion 17.

The membrane 15 is a film of PVPF (polyvinylidene fluoride) material upon which are formed sensor electrodes (not shown) in known manner to provide an electrical output signal responsive to flexure of the film.

An output lead 21 connects the membrane to the valve 4 which includes suitable circuitry to actuate the valve in response to an actuating signal.

In use a user inhales air through the mouthpiece 7 resulting in a drop of air pressure within the mouthpiece. Air flows through the housing 2 from the open end 10 to the outlet 11. The presence of the container 3 in the main tubular portion 6 results in the passageway 9 being constricted adjacent to the open end 10 which tends to enhance the drop in pressure of the air within the mouthpiece 7.

In response to the drop of air pressure within the mouthpiece 7 the membrane 15 flexes such that exposed portions of the membrane 15 bow into the cut-outs 18, 19 and 20 and this flexure of the membrane results in an actuating signal being generated by piezoelectric action in the membrane and transmitted via output lead 21 to the valve 4.

The valve 4 is actuated by the actuating signal and releases a measured dose of medicament into the nozzle fitting 13 from which it is dispensed as an aerosol spray through the nozzle opening 13 into the mouthpiece 7 so as to be entrained in the air flow and hence inhaled by the user.

When the inhalation ceases the membrane relaxes to its rest position in which it lies in contact with the side wall portion 17. During this relaxation of the membrane a signal of opposite polarity is generated by the membrane. The circuitry of the

valve 4 is arranged to not respond to a signal of this reverse polarity.

An alternative apparatus 30 is shown in Figure 3 and is described using corresponding reference numerals to those of Figure 1 where appropriate for corresponding elements.

The alternative apparatus 30 has a pressurised dispensing container 3 having a conventional mechanical valve 31 which is actuated by depression of a valve stem 5 relative to the container. The valve stem 5 is received in a fixed nozzle fitting 12 and the container is moved towards and away from the nozzle fitting by a solenoid operated plunger 32. The plunger 32 is driven by an electrical actuator 33 which is connected to a sensor 14 which corresponds to the sensor 14 of the apparatus of Figures 1 and 2. Sensor 14 is similarly located in a mouthpiece 7 of housing 2.

In use a user inhales air through the mouthpiece 7 and air is drawn through a passageway 9 defined by housing 2. Air pressure within the mouthpiece is decreased by the inhalation so that the membrane 15 flexes so as to bow into the cut-outs 18, 19, and 20 of the support member 16. An actuating signal is transmitted to the actuator 33 resulting in the plunger 32 being moved by solenoid action so as to translate the container 3 towards the nozzle fitting 12. The valve 31 operates to release a medicinal product through the stem 5 which is atomised and injected into the air flow by the nozzle opening 13.

A further alternative apparatus 40 is shown in Figure 4 and will be described using corresponding reference numerals to those of previous Figures where appropriate for corresponding elements.

Apparatus 40 has a housing 41 with a mouthpiece

7 communicating via a tubular duct 42 with an inlet opening 43 arranged such that the inlet opening and mouthpiece 7 are at opposite ends of the tubular duct.

The housing 41 includes a side arm 44 defining a second duct 45 communicating with the first duct 42 at a T-junction 46.

The side arm 44 has an outer end 47 at which is located a piezoelectric atomiser 48 of a type in which liquid from a liquid reservoir 49 is dispensed through a perforate membrane 50 in response to high frequency vibration of the membrane 50 by a piezoelectric element 51.

A side port 52 is formed in the side arm 44 intermediate the T-junction 46 and the atomiser 48 and the side port is closed by an elastomeric diaphragm 53. A piezoelectric membrane 54 of PVPF material is bonded to the diaphragm 53 so as to flex in unison with the diaphragm. The membrane 54 is provided with suitable electrodes (not shown) for sensing piezoelectrically induced voltages resulting from flexure of the membrane and which are connected to an electronic control unit 55 which is operable to actuate the atomiser 48. The membrane 54 and diaphragm 53 constitute a sensor 56 which is responsive to pressure change in the second duct 45.

The inlet opening 43 is defined by an annular formation 57 which provides a constriction to the flow of air through the duct 42.

In use a user inhales air through the mouthpiece 7 and an air flow is established through the duct 42 from the restricted inlet opening 43. A pressure drop established within the duct 42 is communicated to the second duct 45 resulting in inward flexure of the diaphragm 53 and with it the membrane 54. The sensor 56 produces by piezoelectric action an actuating signal transmitted

to the control unit 55 resulting in the atomiser 48 being actuated. A mist of liquid is dispensed from the reservoir 49 through the perforate membrane 50 into the second duct 45 and is drawn into the duct 42 from whence it is inhaled through the mouthpiece 7.

On completion of inhalation the pressure within the ducts 42 and 45 is restored to atmospheric pressure and the diaphragm 53 relaxes to its rest position. During this relaxation a signal of opposite polarity is generated by the sensor 56. The control unit 55 is arranged not to respond to reverse polarity signals.

CLAIMS:

1. Inhalation apparatus for dispensing
inhaled substances comprising a housing defining a
passageway for inhaled air, a dispensing means
operable in response to an electrical actuating
signal to dispense into the passageway a substance to
be inhaled, and a sensor operable to produce the
actuation signal in response to inhalation wherein
the sensor comprises a membrane of piezoelectric
material and support means supporting the membrane
relative to the housing at a location such that the
membrane flexes in response to a change of air
pressure in the passageway to thereby generate the
actuation signal.

2. Inhalation apparatus as claimed in claim 1
wherein the membrane comprises a polymeric
piezoelectric material.

3. Inhalation apparatus as claimed in claim 2
wherein the piezoelectric material is polyvinylidene
fluoride.

4. Inhalation apparatus as claimed in any
preceding claim wherein the support means comprises a
support member cooperating with the housing to clamp
a clamped portion of the membrane in fixed
relationship with the housing, the clamped portion
being peripheral to at least one unclamped portion
which is flexible in response to pressure change in
the passageway.

5. Inhalation apparatus as claimed in claim 4
wherein the membrane overlays a portion of a side
wall defining the passageway.

6. Inhalation apparatus as claimed in any of
claims 1 to 4 wherein the member is mounted on a
resilient diaphragm for flexure in unison with the
diaphragm, the diaphragm being located such that one
side of the diaphragm is exposed to ambient air
pressure and the other side of the diaphragm is
exposed to air within the passageway.

7. Inhalation apparatus substantially as
hereinbefore described with reference to and as shown
in any of the accompanying drawings.

Patents Act 1977
Examiner's report to the Comptroller under
Section 17 (The Search Report)

-10-

Application number

9207490.0

Relevant Technical fields

(1) UK Cl (Edition X) AST TBE, TBC, TED, TED
(2) Int Cl (Edition) A61M

Databases (see over)

(1) UK Patent Office
(2)

Search Examiner

J A WALLIS

Date of Search

22 MAY 1992

Documents considered relevant following a search in respect of claims

ALL

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
	NONE	

-11-

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of
inventive step.

Y: Document indicating lack of inventive step if
combined with one or more other documents of the
same category.

A: Document indicating technological background
and/or state of the art.

P: Document published on or after the declared
priority date but before the filing date of the
present application.

E: Patent documents published on or after, but with
priority date earlier than, the filing date of the
present application.

B: Member of the same patent family,
corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US
patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases
considered for search are also listed periodically in the Official Journal (Patents).